DEC 2 2010

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLVE® EPS ORTHOLOC™ System.

A.1. Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002
Date:	August 9, 2010
Contact Person:	Kelsey Lee Regulatory Affairs Specialist I (901) 290-5909
A.2. Proprietary Name:	**EVOLVE® EPS ORTHOLOC™**
Common Name:	Bone Plate System/Bone Screw System
Device Classification Regulation:	21 CFR 888.3030--Class II
Device Product Code & Panel:	HRS: Single/multiple component metallic bone fixation appliances and accessories. HWC: Screw, fixation, bone 87 Orthopedics
A.3. Predicate Device:	EVOLVE® EPS ORTHOLOC™ System (K100146)

A.4. Device Description

The EVOLVE® EPS OTHOLOC™ System is extended to offer two longer screw lengths and four shorter plates. The driver-screw interface is also being modified. The plates are identical to the predicate in hole/slot placement and depth, plate shape and material. The subject screws have identical profile and thread form. The screws may be used with or without the plates.

The design features of the EVOLVE® EPS ORTHOLOC™ system are substantially equivalent to the design features of the predicate EVOLVE® EPS ORTHOLOC™.

A.5. Intended Use

The subject EVOLVE® EPS ORTHOLOC™ system has the same intended use as the predicate.

The EVOLVE® EPS ORTHOLOC™ is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius and ulna.

A.6. Technological Characteristics Comparison

The subject EVOLVE® EPS ORTHOLOC™ and the legally marketed predicate EVOLVE® EPS ORTHOLOC™ System have identical indications, utilize the same instruments, and are manufactured out of the same materials. The subject and predicate components are fully compatible.

The subject EVOLVE® EPS ORTHOLOC™ adds two additional lengths of screws, four shorter plates, offers a modified drive feature on the screw heads and may be used with or without the plates.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through ultimate torque testing, pull-out data, and off-axis locking comparison. The results of the tests show that the subject EVOLVE® EPS ORTHOLOC™ can be expected to perform at least as well as the legally marketed predicate EVOLVE® EPS ORTHOLOC™.

The safety and effectiveness of the subject EVOLVE® EPS ORTHOLOC™ System is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within this Premarket Notification.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

Substantial equivalence is shown through ultimate torque testing, pull out data and off-axis locking comparison. The materials, indications, screw and thread profiles, and plate shapes and features are identical between the subject and predicate. The subject and predicate differ in drive feature depth, screw lengths and plate lengths; no new questions concerning safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
c/o Ms. Kelsey Lee
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

DEC 2 2010

Re: K102352
Trade/Device Name: EVOLVE® EPS ORTHOLOC™ System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 29, 2010
Received: November 2, 2010

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC 2 2010

Indications for Use

510(k) Number (if known): K102352

Device Name: EVOLVE® EPS ORTHOLOC™ System

Indications For Use:

The EVOLVE® EPS ORTHOLOC™ System is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius and ulna.

Prescription Use __xxx__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102352